

AMENDMENT TO THE CLAIMS

The listing of claims below will replace all prior versions and listings of claims in the application:

1. (Currently amended) A solid unit dosage form wherein said solid unit dosage form is a tablet comprising:
- a) atorvastatin, or a pharmaceutically acceptable salt thereof, and an ~~at least one~~ excipient or combination of excipients
 - b) prepared by direct compression without a granulation step,
 - c) wherein the measured atorvastatin potency of said dosage form shows a relative standard deviation for atorvastatin potency per unit dosage form of not more than about 7.8%, when said unit dosage form is prepared at a rate greater than 10,000 unit dosage forms per hour per single unit dosage form per machine, and;
~~wherein said excipient or combination of excipients comprises greater than about 50 wt% of a diluent or combination of diluents selected from the group of lactose monohydrate, lactose anhydrous, microcrystalline cellulose or sodium chloride; and said excipient or combination of excipients~~ said solid unit dosage form ~~contains less than about 5wt%~~ w/w% of an alkalinizing agent additive.

Claims 2-3 Cancelled.

4. (Currently amended) The solid unit dosage form of Claim 1 wherein said atorvastatin or pharmaceutically acceptable salt thereof is a form of atorvastatin that is at least somewhat disordered or a mixture of crystalline and disordered forms of atorvastatin.

Claims 5-7 cancelled

8. (Currently amended) The solid unit dosage form of atorvastatin according to Claim 1 wherein said unit dosage form contains not more than about 2% total drug related impurities and/or degradants based on the area percent of the impurities and/or

degradants relative to the integrated area of all drug related peaks as determined by HPLC.

9. (Currently amended) The solid unit dosage form of atorvastatin according to Claim 1 wherein said unit dosage form contains not more than about 2% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

10. (Currently amended) The solid unit dosage form of atorvastatin according to Claim 1 wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% total drug related impurities and/or degradants based on the area percent of all drug related peaks relative to the area of the atorvastatin peak as determined by HPLC.

11. (Currently amended) The solid unit dosage form of atorvastatin according to Claim 1 wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

12. (Currently amended) The solid unit dosage form of Claim 1, wherein the composition formed from said excipient or combination of excipients and said atorvastatin or a pharmaceutically acceptable salt thereof has a segregation number of less than 0.6 when tested with a fluidization segregation tester.

Claims 13-17 Cancelled.

Claims 18-30 Cancelled

31. (New) The solid unit dosage form according to claim 1 wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

32. (New) The solid unit dosage form according to claim 31 which contains less than 5 w/w% of a polymeric amide or polymeric amine.

33. (New) The solid unit dosage form according to claim 1 that contains less than 2 w/w% of said alkalinizing agent.

34. (New) The solid unit dosage form according to claim 33 wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

35. (New) The solid unit dosage form according to claim 34 which contains less than 3 w/w% of a polymeric amide or polymeric amine.

36. (New) The solid unit dosage form according to claim 1 that contains less than 1 w/w% of said alkalinizing agent.

37. (New) The solid unit dosage form according to claim 36 wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

38. (New) The solid unit dosage form according to claim 37 which contains less than 2 w/w% of a polymeric amide or polymeric amine.